IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

COLLEGIUM PHARMACEUTICAL, INC.,	)	
	)	
Plaintiff,	)	
v.	)	C.A. No.
	)	
TEVA PHARMACEUTICALS USA, INC.,	)	
	)	
Defendant.	)	

COMPLAINT

Plaintiff Collegium Pharmaceutical, Inc. ("Collegium"), for its Complaint herein, avers as follows:

1. The present complaint asserts counts that relate to Teva Pharmaceuticals USA Inc.'s ("Teva's") submission of Abbreviated New Drug Application ("ANDA") No. 209431 to the U.S. Food, & Drug Administration ("FDA"), under § 505(j)(2)(B) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)(2)(B)), seeking approval to engage in the commercial manufacture, use, sale, offer for sale or importation of Oxycodone Extended-Release Capsules, CII,, 9 mg, 13.5 mg, 18 mg, 27 mg, and 36 mg ("the Teva ANDA Products") before the expiration of, Collegium's U.S. Patents Nos. 7,399,488; 7,771,707; 8,449,909; 8,557,291; 8,758,813; 8,840,928; 9,044,398; 9,248,195; 9,592,200; 9,682,075; 9,737,530 and 9,763,883.

2. The present complaint seeks relief relating to Teva's submission of ANDA No. 209431 seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of the Teva ANDA Products prior to the expiration of eleven of the twelve patents certified by Teva.

NATURE OF THE ACTION

3. This is an action for relief from patent infringement, arising under the patent laws of Title 35, United States Code. Collegium seeks relief from infringement of U.S. Patents Nos. 7,771,707; 8,449,909; 8,557,291; 8,758,813; 8,840,928; 9,044,398; 9,248,195; 9,592,200; 9,682,075; 9,737,530 and 9,763,883 ("Asserted Patents"), which essentially relate to (1) improved abuse-deterrent and tamper-resistant components or formulations of abuse-prone substances, including, *inter alia*, oxycodone and oxycodone salts, (2) methods of making these abuse-deterrent, tamper-resistant formulations and (3) methods of treating pain using these formulations. Teva has infringed the Patents under 35 U.S.C. § 271(e)(2)(A) by filing ANDA No. 209431 on the Teva ANDA Products and has expressed its intent to conduct activities that will infringe under 35 U.S.C. §§ 271(a), (b), (c) and (g) by actual marketing of the Teva ANDA Products.

THE PARTIES

4. Collegium is a corporation organized and existing under the laws of the Commonwealth of Virginia, having its principal place of business at 780 Dedham Street, Suite 800, Canton, MA 02021. Collegium is the owner of the Patents. Collegium is also the holder of NDA No. 208090 for XTAMPZA® ER (oxycodone) extended-release capsules, CII, for oral use, for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate, and is involved in the sale of XTAMPZA® in the United States.

5. On information and belief, Defendant Teva Pharmaceuticals USA, Inc. is a corporation organized and existing under the laws of the State of Delaware, with a place of business at 1090 Horsham Road, North Wales, Pennsylvania, and having designated its

registered agent for the State of Delaware as Corporate Creations Network Inc., 3411 Silverside Road, #104 Tatnall Building, Wilmington, Delaware.

6. On information and belief, Teva is in the business of, among other things, manufacturing, marketing, distributing, offering for sale, and selling generic drug products. As a part of this business, on information and belief, Teva files ANDAs with the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of generic versions of drug products that infringe United States patents. On information and belief, as part of these ANDAs, Teva USA, files Paragraph IV Certifications to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic drug products prior to the expiration of United States patents that cover such products.

7. On information and belief, following any FDA approval of ANDA No. 209431, Teva will market, distribute, offer for sale and sell Teva's ANDA Product throughout the United States and within Delaware.

8. On information and belief, following any FDA approval of ANDA No. 209431, Teva knows and intends that its ANDA Product will be marketed, used, distributed, offered for sale and sold in the United States and within Delaware.

JURISDICTION AND VENUE

9. This action arises under the patent laws of the United States, including 35 U.S.C. § 271.

10. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

11. This Court has personal jurisdiction over Teva, and venue is proper in this Judicial District under 28 U.S.C. §§ 1391(b) and (c) and § 1400(b), because Teva is incorporated in this Judicial District.

12. Teva is in the business of preparing pharmaceuticals that it distributes in the State of Delaware and throughout the United States.

13. Upon information and belief, if ANDA No. 209431 is approved, the Teva ANDA Products will, among other things, be marketed and distributed in Delaware, and/or prescribed by physicians practicing and dispensed by pharmacies located within Delaware, all of which have a substantial effect on Delaware.

THE ASSERTED PATENTS

14. The FDA *Approved Drug Products with Therapeutic Equivalence Evaluations* ("*Orange Book*") identifies drug products that have been approved by the FDA under the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 301 et seq.). The *Orange Book* also provides a listing of certain patents that cover a given drug product or the use thereof.

15. Collegium is the lawful owner of all right, title and interest in U.S. Pat. No. 7,771,707 ("the '707 Patent") (Ex. A hereto), entitled *Abuse-Deterrent Drug Formulations*, granted August 10, 2010, from application S/N 11/149,867 (filed June 10, 2005), with priority to U.S. Provisional Application S/N 60/579,191 (filed June 12, 2004). The inventors of the '707 Patent are Jane Hirsh; Alison B. Fleming; Roman V. Rariy and Alexander M. Klibanov. Collegium is the assignee of the '707 Patent, which is currently scheduled to expire on March 24, 2025.

16. Collegium is the lawful owner of all right, title and interest in U.S. Pat. No. 8,449,909 ("the '909 Patent") (Ex. B hereto), entitled *Abuse-Deterrent Drug Formulations*, granted May 28, 2013, from application S/N 12/823,628 (filed June 25, 2010), and is a continuation of application S/N 11/149,867 (filed June 10, 2005, now the '707 Patent), with priority to U.S. Provisional Application S/N 60/579,191 (filed June 12, 2004). The inventors named on the face of the '909 Patent are Jane Hirsh; Alison B. Fleming; Roman V. Rariy and

Alexander M. Kilbanov. Collegium is the assignee of the ’909 Patent, which is currently scheduled to expire on March 24, 2025.

17. Collegium is the lawful owner of all right, title and interest in U.S. Pat. No. 8,557,291 (“the ’291 Patent”) (Ex. C hereto), entitled *Abuse-Deterrent Pharmaceutical Compositions of Opioids and Other Drugs*, granted October 15, 2013, from application 5/N 12/473,073 (filed May 27, 2009), and is a continuation-in-part of abandoned application S/N 12/112,993 (filed April 30, 2008), which is a divisional of application S/N 10/614,866 (filed July 7, 2003, now the ’488 Patent), with priority to U.S. Provisional applications S/Ns 60/393,876 (filed July 5, 2002); 60/436,523 (filed December 23, 2002); 60/443,226 (filed January 28, 2003); 60/463,514 (filed April 15, 2003); and, 60/463,518 (filed April 15, 2003), and is also a continuation-in-part of abandoned application S/N 12/112,937 (filed April 30, 2008), which is a continuation-in-part of application S/N 10/614,866 (filed July 7, 2003, now the ’488 Patent), with priority to U.S. Provisional Applications S/Ns 60/393,876 (filed July 5, 2002); 60/436,523 (filed December 23, 2002); 60/443,226 (filed January 28, 2003); 60/463,514 (filed April 15, 2003); and 60/463,518 (filed April 15, 2003); and is a continuation-in-part of application S/N 11/149,867 (filed June 10, 2005, now the ’707 patent), which claims priority to U.S. Provisional application S/N 60/579,191 (filed June 12, 2004). The inventors of the ’291 patent are Roman V. Rariy; Alison B. Fleming; Jane Hirsh and Alexander M. Klibanov. Collegium is the assignee of the '291 patent, which is currently scheduled to expire on March 21, 2025.

18. Collegium is the lawful owner of all right, title and interest in U.S. Pat. No. 8,758,813 (“the ’813 Patent”) (Ex. D hereto), entitled *Abuse-Deterrent Drug Formulations*, issued June 24, 2014, from application S/N 13/870,690 (filed April 25, 2013), and is a continuation of application S/N 12/823,628 (filed June 25, 2010, now the ’909 Patent), which is

a continuation of application S/N 11/149,867 (filed June 10, 2008, now the ’707 Patent), with priority to U.S. Provisional Application S/N 60/579,191 (filed June 12, 2004). The inventors of the ’291 Patent are Jane Hirsh; Alison Fleming; Roman Rariy and Alexander M. Klibanov. Collegium is the assignee of the ’813 Patent, which is currently scheduled to expire on June 10, 2025.

19. Collegium is the lawful owner of all right, title and interest in U.S. Pat. No. 8,840,928 (“the ’928 Patent”) (Ex. E hereto), entitled *Tamper-Resistant Pharmaceutical Compositions of Opioids and Other Drugs*, granted September 23, 2014, from application S/N 12/965,572 (filed December 10, 2010), with priority to U.S. Provisional Application S/N 61/285,231 (filed December 10, 2009), which is a continuation-in-part of abandoned application S/N 12/112,937 (filed April 30, 2008), which is a continuation-in-part of application S/N 10/614,866 (filed July 7, 2003, now the ’488 Patent), and a continuation-in-part of application S/N 12/473,073 (filed May 27, 2009, now the ’291 patent), and a continuation-in-part of abandoned application S/N 12/112,993 (filed April 30, 2008), which is a divisional of application S/N 10/614,866 (filed July 7, 2003, now the ’488 patent), both of which having priority to U.S. Provisional Applications S/Ns 60/393,876 (filed July 5, 2002); 60/436,523 filed December 23, 2002); 60/443,226 (filed January 28, 2003); 60/463,514 (filed April 15, 2003) and, 60/463,518 (filed April 15, 2003). The inventors of the ’928 Patent are Roman V. Rariy; Alison B. Fleming; Jane C. Hirsh; Said Saim and, Ravi K. Varanasi. Collegium is the assignee of the ’928 Patent, which is currently scheduled to expire on July 7, 2023.

20. Collegium is the lawful owner of all right, title and interest in U.S. Pat. No. 9,044,398 (“the ’398 Patent”) (Ex. F hereto), entitled *Tamper-Resistant Pharmaceutical Compositions of Opioids and Other Drugs,* issued June 2, 2015, from application S/N

13/551,455 (filed July 17, 2012), and is a continuation of abandoned application S/N 12/112,993 (filed April 30,2008), which is a divisional of application S/N 10/614,866 (filed July 7, 2002, now the ’488 Patent), with the benefit of U.S. Provisional Applications S/Ns 60/393,876 (filed July 5, 2002); 60/436,523 (filed December 23, 2002); 60/443,226 (filed January 28, 2003); 60/463,514 (filed April 15, 2003) and 60/463,518 (filed April 15, 2003). The inventors of the ’398 Patent are Jane Hirsh; Alexander M. Klibanov; Timothy M. Swager; Stephen L. Buchwald; Whe Yong Lo; Alison Fleming and Roman V. Rariy. Collegium is the assignee on the face of the ’398 Patent, which is currently scheduled to expire on July 7, 2023.

21. Collegium is the lawful owner of all right, title and interest in U.S. Pat. No. 9,248,195 (“the ’195 Patent”) (Ex. G hereto), entitled *Abuse-Deterrent Pharmaceutical Compositions of Opioids and Other Drugs,* granted February 2, 2016, from application S/N 14/054,513 (filed October 15, 2013), which is a divisional of application S/N 12/473,073 (filed May 27, 2009, now the ’291 Patent), which is a continuation-in-part of abandoned application S/N 12/112,993 (filed April 30, 2008), which is a divisional of application S/N 10/614,866 (filed July 7, 2003, now the ’488 Patent), with priority to U.S. Provisional Applications S/Ns 60/393,876 (filed July 5, 2002); 60/436,523 (filed December 23, 2002); 60/443,226 (filed January 28, 2003); 60/463,514 (filed April 15, 2003); 60/463,518 (filed April 15, 2003); application S/N 12/473,073 (filed May 27, 2009, now the ’291 patent), is also a continuation-in-part of abandoned application S/N 12/112,937 (filed April 30, 2008), which is a continuation-in-part of application S/N 10/614,866 (filed July 7, 2003, now the ’488 patent), with priority to U.S. Provisional Applications S/Ns 60/393,876 (filed July 5, 2002); 60/436,523 (filed December 23, 2002); 60/443,226 (filed January 28, 2003); 60/463,514 (filed April 15, 2003) and 60/463,518 (filed April 15, 2003); application S/N 12/473,073 (filed May 27, 2009, now the ’291 Patent), is

also a continuation-in-part of application S/N 11/149,867 (filed June 10, 2005, now the ’707 Patent), with priority to U.S. Provisional Application S/N 60/579,191 (filed June 12, 2004). The inventors of the ’195 Patent are Roman V. Rariy, Alison B. Fleming, Jane Hirsh and Alexander M. Klibanov. Collegium is the assignee of the ’195 Patent, which is currently scheduled to expire on July 7, 2023.

22. Collegium is the lawful owner of all right, title and interest in U.S. Pat. No. 9,592,200 (“the ’200 Patent”) (Ex. H hereto), entitled *Abuse-Deterrent Pharmaceutical Compositions of Opioids and Other Drugs,* granted March 14, 2017, from application S/N 14/946,275 (filed November 19, 2015), which is a continuation of application S/N 14/054,513 (filed October 15, 2013, now the ’195 Patent), which is a divisional of application S/N 12/473,073 (filed May 27, 2009, now the ’291 Patent), which is a continuation-in-part of abandoned application S/N 12/112,993 (filed April 30, 2008), which is a divisional of application S/N 10/614,866 (filed July 7, 2003, now the ’488 Patent), with priority to U.S. Provisional applications S/Ns 60/393,876 (filed July 5, 2002); 60/436,523 (filed December 23, 2002); 60/443,226 (filed January 28, 2003); 60/463,514 (filed April 15, 2003); 60/463,518 (filed April 15, 2003) and application S/N 12/473,073 (filed May 27, 2009, now the ’291 Patent), which is a continuation-in-part of abandoned application S/N 12/112,937 (filed April 30, 2008), which is a continuation-in-part of application S/N 10/614,866 (filed July 7, 2003, now the ’488 Patent), with priority to Provisional Applications S/Ns 60/393,876 (filed July 5, 2002); 60/436,523 (filed December 23, 2002); 60/443,226 (filed January 28, 2003); 60/463,514 (filed April 15, 2003) and, 60/463,518 (filed April 15, 2003); and, application S/N 12/473,073 (filed May 26, 2009, now the ’291 Patent), which is also a continuation-in-part of application S/N 11/149,867 (filed June 10, 2005, now the ’707 Patent), which claims priority to Provisional application S/N 60/579,191

(filed June 12, 2004). The inventors of the ’200 Patent are Roman V. Rariy, Alison B. Fleming, Jane Hirsh and Alexander M. Klibanov. Collegium is the assignee on the face of the ’200 Patent, which is currently scheduled to expire on July 7, 2023.

23. Collegium is the lawful owner of all right, title and interest in U.S. Pat. No. 9,682,075 (“the ’075 Patent”) (Ex. I hereto), entitled *Tamper-Resistant Pharmaceutical Compositions of Opioids and Other Drugs,* granted June 20, 2017, from application S/N 14/320,086 (filed June 30, 2014), which is a continuation of application S/N 12/965,572 (filed December 10, 2010, now the ’928 Patent), with priority to Provisional application S/N 61/285,231 (filed December 10, 2009). The inventors of the ’075 Patent are Roman Rariy; Alison Fleming; Jane C. Hirsh; Said Saim and Ravi K. Varanasi. Collegium is the assignee of the '075 Patent, which is currently scheduled to expire on December 10, 2030.

24. Collegium is the lawful owner of all right, title and interest in U.S. Pat. No. 9,737,530 (“the ’530 Patent”) (Ex. J hereto), entitled *Process of Making Stable Abuse-Deterrent Oral Formulations*, granted August 22, 2017, from application S/N 15/255,859 (filed September 2, 2016), with priority to Provisional application S/N 62/353,839 (filed June 23, 2016). The inventors named on the face of the ’530 Patent are Said Saim; Alison B. Fleming and Ravi K. Varanasi. Collegium is the assignee of the ’530 Patent, which is currently scheduled to expire on September 2, 2036.

25. Collegium is the lawful owner of all right, title and interest in U.S. Pat. No. 9,763,883 (“the ’883 Patent”) (Ex. K hereto), granted *Abuse-Deterrent Drug Formulations,* issued September 19, 2017, from application S/N 14/147,088 (filed January 3, 2014), which is a continuation of application S/N 13/870,690 (filed April 25, 2013), which is a continuation of application S/N 12/823,628 (filed June 25, 2010, now the ’909 Patent), which is a continuation

of application S/N 11/149,867 (filed June 10, 2005, now the ’707 Patent), with priority to Provisional application S/N 60/579,191 (filed June 12, 2004). The inventors of the ’883 Patent are Jane Hirsh; Alison Fleming; Roman Rariy and Alexander Klibanov. Collegium is the assignee of the ’883 Patent, which is scheduled to expire on July 7, 2023.

DRUG-ABUSE-DETERRENT TECHNOLOGY

26. Oxycodone, morphine, and other opioid analgesics are therapeutically useful and effective medications, e.g., as pain relievers, when administered orally. Unfortunately, they also pose a severe threat for willful abuse due to their ability to alter mood and/or cause a sense of euphoria. Conventional (i.e., non-abuse deterrent) available sustained release formulations of such drugs, which contain a relatively large amount of drug intended to be released from the formulation over an extended period of time, are particularly attractive to abusers since the sustained release coating can be destroyed by crushing or grinding the formulation. The crushed material no longer controls the release of drug. Depending on the drug, abusers can then (1) snort the material, (2) swallow the material or (3) dissolve the material in water and subsequently inject it intravenously. The dose of drug contained in the formulation is thus absorbed immediately through the nasal or GI mucosa (for snorting or swallowing, respectively) or is administered systemically in a bolus via the circulatory system (for IV injection). These abuse methods result in the rapid bioavailability of relatively high doses of drug, giving the abuser a "high". Since relatively simple methods (crushing, grinding, chewing and/or dissolution in water) can be used to transform conventional formulations into an abusable form, they provide virtually no deterrent to a potential abuser.

27. OxyContin® is supplied in a controlled-release dosage form and is intended to provide up to 12 hours of relief from moderate to severe pain. Even though the formulation for

OxyContin® has been changed to implement tablet hardness as an abuse-deterrence mechanism in reformulated OxyContin®, the tablets can still be crushed. When a crushed tablet is swallowed, snorted into the nostrils, or dissolved and subsequently injected intravenously, the controlled-release mechanism is destroyed and a potentially lethal dose of oxycodone becomes bioavailable. Thus, reformulated OxyContin® is still required to carry a black-box warning, which states: "crushing, chewing, or dissolving OxyContin tablets can cause rapid release and absorption of a potentially fatal dose of oxycodone."

28. The warning specifically states that the tablet must be taken whole and only by mouth.

29. The problems with abuse and diversion of oxycodone are well documented over many years. Some of these reported cases have been associated with serious consequences including death.

30. The problems with abuse are significant and longstanding, and efforts to design new abuse-resistant or abuse-deterrent formulations have resulted in availability of a limited number of sustained-release opioid formulations with features to deter abuse. Some formulations have been designed to prevent the injection of compositions meant for oral administration, e.g. the incorporation of an ingestible solid which causes an increase in viscosity upon exposure to aqueous solutions.

31. It should be noted that although these compositions preclude abuse by injection, this approach fails to prevent abuse by crushing and swallowing or snorting the formulation.

32. Other patented approaches have described formulations containing a combination of opioid agonists and antagonists, in which the antagonist does not block the therapeutic effect when the admixture is administered orally, but which does not produce analgesia, euphoria or

physical dependence when administered parenterally by an abuser. Some patents describe oral dosage forms including a combination of an orally active opioid agonist and an orally active opioid antagonist in a ratio that, when delivered orally, is analgesically effective but that is aversive in a physically dependent subject. While such a formulation may be successful in deterring abuse, it also has the potential to produce adverse effects in legitimate patients.

33. It is thus an object of Collegium's Patents to provide a pharmaceutical composition that significantly reduces the potential for improper administration or use of drugs but which, when administered as directed, is capable of delivering a therapeutically effective dose. Abuse-deterrent and tamper-resistant pharmaceutical compositions have been developed to reduce the likelihood of improper administration of drugs, especially drugs such as opioids.

34. In one, preferred, embodiment, the drug is modified to increase its lipophilicity by forming a salt between the drug and one or more fatty acids or amines, wherein the concentration of the one or more fatty acids or amines is one to fifteen times the molar amount of the active agent, preferably two to ten times the molar amount of the active agent. In one embodiment the modified drug is homogeneously dispersed within microparticles composed of a material that is either slowly soluble or insoluble in water. The abuse-deterrent composition prevents the immediate release of a substantial portion of drug, even if the physical integrity of the formulation is compromised (for example, by chopping with a blade or crushing) and the resulting material is placed in water, snorted, or swallowed. However, when administered as directed, the drug is slowly released from the composition as the composition is broken down or dissolved gradually within the GI tract by a combination of enzymatic degradation, surfactant action of bile acids, and mechanical erosion.

35. Collegium's unique formulation earned it a New Product marketing exclusivity until April 26, 2019 at the time of approval. More recently, on November 6, 2017, the FDA approved Collegium's sNDA, which included three main changes:

- The addition of comparative oral pharmacokinetic data, collected in two completed clinical studies evaluating the effect of physical manipulation by crushing XTAMPZA® ER compared with the abuse-deterrent of OxyContin® (oxycodone hydrochloride extended-release tablets) and a control (oxycodone immediate release (IR))
- Results of an oral human abuse potential study showing statistically lower "Drug Liking" and "Take Drug Again" scores for XTAMPZA® ER by comparison to oxycodone IR) and
- The additional of an oral abuse deterrent claim into the label indicating that XTAMPZA® ER has physiochemical properties that are expected to reduce abuse by the oral route.

36. With approval of the sNDA, XTAMPZA® ER, an embodiment of the patented Collegium formulations, was the first single-entity oxycodone formulation to be recognized by FDA to have abuse-deterrent properties with respect to all three of the most common routes of abuse- i.e., nasal, IV and oral routes.

37. Now Teva states its intention to launch a copy of Collegium's XTAMPZA®: Teva provided Collegium with a Notice of Patent Certification asserting it intends to launch its copy before Collegium's patents to its superior abuse-deterrent product expire. Teva's Detailed Statement, sent with its Notice of Patent Certification, critically does not even allege non-infringement for a wide swathe of the claims in Collegium's patent. On this basis alone, it is

apparent that Teva intends to launch essentially a copy of Collegium's superior XTAMPZA® product, with its uniquely effective abuse-deterrent properties.

TEVA'S ANDA

38. Upon information and belief, Teva submitted ANDA No. 209431 to the FDA under § 505(j)(2)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)(2)(B)), seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of the Teva ANDA Products prior to the expiration of the Patents.

39. Upon information and belief, Teva's ANDA No. 209431 contains a "Paragraph IV" certification under 21 U.S.C. § 355(b)(2)(A)(iv) alleging that the Patents, all listed in the FDA's *Orange Book* as covering the drug XTAMPZA®, which is the subject of approved NDA No. 208090, is "invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of [the Teva ANDA Products]."

40. In a letter dated January 9, 2018 addressed to Collegium, and received on January 10, 2018, Teva provided "Notice" with respect to the proposed Teva ANDA Products under 21 U.S.C. § 355(j)(2)(B)(ii)-(iv) and 21 C.F.R. § 314.95(c) and/or § 314.95(d).

41. The Detailed Statement attached to Teva's Notice repeatedly fails to allege non-infringement of claims of the Asserted Patents. The only reasonable assumption is that Teva intends to launch essentially a copy of Collegium's unique, patented abuse-deterrent oxycodone product.

CLAIMS FOR RELIEF:

COUNT I

(Teva's Filing of the ANDA Constitutes Infringement, and the Sale and Use of the Teva ANDA Products Will Constitute Infringement, of the '707 Patent)

42. Collegium incorporates by reference and realleges paragraphs 1-41 above as though fully restated herein.

43. Teva's submission of its ANDA was an act of infringement of the Asserted Patents under the United States Patent Law, 35 U.S.C. § 271(e)(2)(A).

44. Upon information and belief, the Teva ANDA Products infringe at least claims 1, 2, 3, 5, 6, 8, 10 and 13–19 of the '707 Patent, which recite, *inter alia*, a solid orally administrable abuse-deterrent pharmaceutical composition of a pharmaceutically active agent prone to abuse, the composition comprising: a mixture of a therapeutically effective amount of the pharmaceutically active agent prone to abuse, and one or more fatty acids or fatty amines present in molar excess relative to the pharmaceutically active agent, wherein the pharmaceutically active agent comprises an effective amount of a fatty acid or fatty amine salt of the pharmaceutically active agent prone to abuse.

COUNT II

(Teva's Filing of the ANDA Constitutes Infringement, and the Sale and Use of the Teva ANDA Products Will Constitute Infringement, of the '909 Patent)

45. Collegium incorporates by reference and realleges paragraphs 1-44 above as though fully restated herein.

46. Teva's submission of its ANDA was an act of infringement of the Asserted Patents under the United States Patent Law, 35 U.S.C. § 271(e)(2)(A).

47. Upon information and belief, the Teva ANDA Products infringe at least claims 1–8 and 13–20 of the '909 Patent, which recite, *inter alia*, a therapeutically effective pharmaceutical composition comprising solid microparticles, wherein the microparticles comprise: a. an active agent, b. one or more fatty acids, and c. one or more carrier materials selected from the group consisting of waxes or wax-like substances and mixtures thereof; wherein the active agent comprises a fatty acid salt of oxycodone, and the one or more fatty acids are present in an amount ranging from 6.9 to 15 times the molar amount of active agent.

COUNT III

(Teva's Filing of the ANDA Constitutes Infringement, and the Sale and Use of the Teva ANDA Products Will Constitute Infringement, of the '291 Patent)

48. Collegium incorporates by reference and realleges paragraphs 1-47 above as though fully restated herein.

49. Teva's submission of its ANDA was an act of infringement of the Asserted Patents under the United States Patent Law, 35 U.S.C. § 271(e)(2)(A).

50. Upon information and belief, the Teva ANDA Products infringe at least claims 1–11, 13 and 14 of the '291 Patent, which recite, *inter alia*, an abuse-deterrent oral dosage form comprising a plurality of microparticles, where each microparticle comprises: a fatty acid salt of one or more drugs prone to abuse, including in a solidified solution; and one or more carrier material(s) comprising fats, fatty substances, waxes, wax-like substances or mixtures thereof wherein the oral dosage form retards the release of the one or more drugs prone to abuse, even if the physical integrity of the dosage form is compromised and the compromised dosage form is placed in water.

COUNT IV

(Teva's Filing of the ANDA Constitutes Infringement, and the Sale and Use of the Teva ANDA Products Will Constitute Infringement, of the '813 Patent)

51. Collegium incorporates by reference and realleges paragraphs 1-50 above as though fully restated herein.

52. Teva's submission of its ANDA was an act of infringement of the Asserted Patents under the United States Patent Law, 35 U.S.C. § 271(e)(2)(A).

53. Upon information and belief, Teva will induce infringement by the sale of the Teva ANDA Products of at least claims 1–6 and 8 of the '813 Patent, which recite, *inter alia*, a method for the management of pain comprising administering to a patient in need thereof a therapeutically effective pharmaceutical composition comprising solid microparticles, wherein the microparticles comprise: a) an active agent, b) one or more fatty acids, and c) one or more carrier materials selected from the group consisting of waxes or wax-like substances and mixtures thereof; wherein the active agent comprises a fatty acid salt of oxycodone, and the one or more fatty acids are present in an amount ranging from 6.9 to 15 times the molar amount of the active agent.

COUNT V

(Teva's Filing of the ANDA Constitutes Infringement, and the Sale and Use of the Teva ANDA Products Will Constitute Infringement, of the '928 Patent)

54. Collegium incorporates by reference and realleges paragraphs 1-53 above as though fully restated herein.

55. Teva's submission of its ANDA was an act of infringement of the Asserted Patents under the United States Patent Law, 35 U.S.C. § 271(e)(2)(A).

56. Upon information and belief, the Teva ANDA Products are covered by, and Teva will induce infringement by the sale of the Teva ANDA Products of, at least claims 1–5, 17–19, 26 and 27 of the '928 Patent, which recite, *inter alia*, a tamper resistant pharmaceutical composition comprising a plurality of solid particles each particle comprising a solid solution comprising: (a) one or more drugs prone to abuse; and (b) one or more fatty acids; wherein the one or more drugs interact ionically with the one or more fatty acids; and the one or more fatty acids comprise at least about 42%-69% by weight of the particle.

COUNT VI

(Teva's Filing of the ANDA Constitutes Infringement, and the Sale and Use of the Teva ANDA Products Will Constitute Infringement, of the '398 Patent)

57. Collegium incorporates by reference and realleges paragraphs 1-56 above as though fully restated herein.

58. Teva's submission of its ANDA was an act of infringement of the Asserted Patents under the United States Patent Law, 35 U.S.C. § 271(e)(2)(A).

59. Upon information and belief, the Teva ANDA Products infringe at least claims 1–11 of the '398 Patent, which recite, *inter alia*, an abuse-deterrent pharmaceutical composition comprising a plurality of microparticles, where each microparticle comprises: a) a lipophilic drug derivative comprising a drug prone to abuse and a fatty acid, and b) one or more carrier material(s) selected from the group consisting of fats, fatty substances, waxes, wax-like substances, and mixtures thereof; wherein manufacturing said microparticles comprises solubilizing the lipophilic drug derivative in molten carrier material or dissolving the lipophilic drug derivative with the carrier material in a co-solvent; and wherein the release of a portion of incorporated drug is retarded when the physical integrity of the composition is compromised and the compromised composition is exposed to water.

COUNT VII

(Teva's Filing of the ANDA Constitutes Infringement, and the Sale and Use of the Teva ANDA Products Will Constitute Infringement, of the '195 Patent)

60. Collegium incorporates by reference and realleges paragraphs 1-59 above as though fully restated herein.

61. Teva's submission of its ANDA was an act of infringement of the Asserted Patents under the United States Patent Law, 35 U.S.C. § 271(e)(2)(A).

62. Upon information and belief, Teva will induce infringement by the sale of the Teva ANDA Products of at least claims 1–11 of the '195 Patent, which recite, *inter alia*, a method of administering an abuse-deterrent pharmaceutical composition comprising orally administering to a patient in need thereof an abuse-deterrent oral dosage form comprising a plurality of microparticles, where each microparticle comprises: a fatty acid salt of one or more drugs prone to abuse; and one or more carrier material(s) comprising fats, fatty substances, waxes, wax-like substances or mixtures thereof wherein the oral dosage form retards the release of the one or more drugs prone to abuse, even if the physical integrity of the dosage form is compromised and the compromised dosage form is placed in water.

COUNT VIII

(Teva's Filing of the ANDA Constitutes Infringement, and the Sale and Use of the Teva ANDA Products Will Constitute Infringement, of the '200 Patent)

63. Collegium incorporates by reference and realleges paragraphs 1-62 above as though fully restated herein.

64. Teva's submission of its ANDA was an act of infringement of the Asserted Patents under the United States Patent Law, 35 U.S.C. § 271(e)(2)(A).

65. Upon information and belief, the Teva ANDA Products infringe at least claims 1–13, 15, 16 and 18 of the ’200 Patent, which recite, *inter alia*, an abuse-deterrent oral dosage form comprising a plurality of microparticles, wherein each microparticle comprises a homogenous single phase comprising: (a) oxycodone; and (b) one or more fatty acids; wherein the molar ratio of fatty acid to oxycodone is in excess of about 7:1 and the oxycodone is in the form of a fatty acid salt.

COUNT IX

(Teva’s Filing of the ANDA Constitutes Infringement, and the Sale and Use of the Teva ANDA Products Will Constitute Infringement, of the ’075 Patent)

66. Collegium incorporates by reference and realleges paragraphs 1-65 above as though fully restated herein.

67. Teva’s submission of its ANDA was an act of infringement of the Asserted Patents under the United States Patent Law, 35 U.S.C. § 271(e)(2)(A).

68. Upon information and belief, the Teva ANDA Products infringe at least claims 1, 3–8 and 12 of the ’075 Patent, which recite, *inter alia*, a tamper resistant pharmaceutical composition comprising a plurality of solid particles each particle comprising: (a) one or more drugs prone to abuse; (b) one or more waxes, wax-like substances or mixtures thereof; and (c) one or more fatty acids present at 42%-69% by weight of the particle wherein the particles have a median particle size (D[0.5]) between about 200 microns and about 400 microns; and wherein the drug is oxycodone or a pharmaceutically acceptable salt thereof and after oral administration as directed a therapeutically effective amount of drug is released over a period of 6-24 hours; and the composition maintains a slow release of drug even if the particles are crushed with a mortar and pestle and swallowed.

COUNT X

(Teva's Filing of the ANDA Constitutes Infringement, and the Sale and Use of the Teva ANDA Products Will Constitute Infringement, of the '530 Patent)

69. Collegium incorporates by reference and realleges paragraphs 1-68 above as though fully restated herein.

70. Teva's submission of its ANDA was an act of infringement of the Asserted Patents under the United States Patent Law, 35 U.S.C. § 271(e)(2)(A).

71. Upon information and belief, the Teva ANDA Products are covered by, and Teva will induce infringement by the sale of the Teva ANDA Products of, at least claims 1, 7 and 10–19 of the '530 Patent, which recite, *inter alia*, a process comprising: a. Preparing a mixture comprising: (i) one or more drugs, one or more pharmaceutically acceptable waxes, and one or more pharmaceutically acceptable fatty acids, or (ii) one or more drugs in the form of a fatty acid salt and one or more pharmaceutically acceptable waxes, at a temperature sufficient to form a substantially homogeneous melt; b. forming solid microparticles from the substantially homogeneous melt; c. optionally further formulating the solid microparticles with additional pharmaceutically acceptable excipients, and d. curing the solid microparticles or formulated microparticles at a temperature within the range of 25° C. up to and including the inversion temperature, for a minimum of about 48 hours.

COUNT XI

(Teva's Filing of the ANDA Constitutes Infringement, and the Sale and Use of the Teva ANDA Products Will Constitute Infringement, of the '883 Patent)

72. Collegium incorporates by reference and realleges paragraphs 1-71 above as though fully restated herein.

73. Teva's submission of its ANDA was an act of infringement of the Asserted Patents under the United States Patent Law, 35 U.S.C. § 271(e)(2)(A).

74. Upon information and belief, the Teva ANDA Products infringe at least claims 1–8 and 11–13 of the '883 Patent, which recite, *inter alia*, an abuse-deterrent, therapeutically effective pharmaceutical composition comprising solid microparticles, wherein the microparticles comprise: a. a fatty acid salt of a basic active agent prone to abuse, and b. one or more carrier materials selected from the group consisting of waxes or wax-like substances and mixtures thereof; wherein the process of making the microparticles comprises dissolving the active agent in free base form in a melt comprising one or more fatty acids, thereby forming a salt between the active agent and the one or more fatty acids, and wherein the one or more fatty acids are present in molar excess relative to the active agent.

COUNT XII

(Teva's Filing of the ANDA Constitutes Infringement, and Teva Will Induce Third Parties to Infringe the Asserted Patents, or Contribute to the Infringement by Third Parties of the Asserted Patents)

75. Collegium incorporates by reference and realleges paragraphs 1-74 above as though fully restated herein.

76. Teva's submission of its ANDA was an act of infringement of the under the United States Patent Law, 35 U.S.C. § 271(e)(2)(A).

77. Upon information and belief, Teva's commercial manufacture, use, sale, offer for sale and/or importation of the Teva ANDA Products will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the Asserted Patents under 35 U.S.C. §§ 271(a), (b), (c), and (g).

78. The Teva ANDA Products constitute a material part of the inventions covered by the claims of the Asserted Patents and are not suitable for substantial noninfringing use.

79. Teva, through at least its labeling, will intentionally induce infringement of the Asserted Patents by at least patients who have taken the Teva ANDA Products and manufacturers that manufactured the Teva ANDA Products and/or the API therefor, including manufacturers that manufacture the Teva ANDA Products and/or the API therefor jointly.

PRAYER FOR RELIEF

WHEREFORE, Collegium prays for judgment:

A. Adjudging that Teva has infringed, and that Teva's commercial sale, offer for sale, use, manufacture, and/or importation of the Teva ANDA Products will infringe, induce infringement of, and/or contribute to the infringement of the Asserted Patents.;

B. Adjudging, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Teva's NDA No. 209431, under § 505(j)(2)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)(2)(B)), to be a date not earlier than the date of expiration of the Asserted Patents plus any additional periods of exclusivity;

C. Preliminarily and permanently enjoining, pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283 and Rule 65, Fed. R. Civ. P., Teva, its officers, partners, agents, servants, employees, parents, subsidiaries, divisions, affiliate corporations, other related business entities, and all other persons acting in concert, participation, or in privity with them, and their successors and assigns, from any commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any drug product that infringes the Asserted Patents;

D. Declaring this an exceptional case and awarding Collegium its attorneys' fees, as provided by 35 U.S.C. §§ 271(e)(4) and 285; and

E. Awarding Collegium such other and further relief as this Court may deem just and proper.

/s/ Frederick L. Cottrell, III
Frederick L. Cottrell, III (#2555)
Kelly E. Farnan (#4395)
Christine D. Haynes (#4697)
Richards, Layton & Finger, P.A.
920 N. King Street
Wilmington, Delaware 19801
302-651-7700
Cottrell@rlf.com
Farnan@rlf.com
Haynes@rlf.com

Attorneys for Plaintiff
Collegium Pharmaceutical, Inc.

OF COUNSEL:

Jake M. Holdreith
Robins Kaplan LLP
800 LaSalle Avenue Suite 2800
Minneapolis, MN 55402
612-349-8483

Jeffrey Alan Hovden
Robins Kaplan LLP
399 Park Avenue Suite 3600
New York, NY 10022
212-980-7400

Dated: February 22, 2018